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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,229	06/25/2001	Richard Ian Christopherson	DAVI139.001A	2287

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EXAMINER

SMITH, CAROLYN L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,229

Applicant(s)

CHRISTOPHERSON ET AL.

Examiner

Carolyn L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58,69 and 71-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58,69 and 71-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3706,4706, 5206</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission, filed 4/7/06, has been entered.

Amended claim 58, filed 4/7/06, is acknowledged.

Claims herein under examination are 58, 69, and 71-74.

Information Disclosure Statements

The information disclosure statement (IDS) submitted on 4/7/06 and 5/2/06 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner. The IDS filed 3/7/06 is an exact copy of the one filed 4/7/06. The IDS filed 4/7/06 has been considered in full. In order to avoid duplication upon printing, the references cited in the IDS filed 3/7/06 have been crossed out.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, such as on page 55, line 19. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58, 69, and 71-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 58 recites “wherein the pattern of expression of the 7 to about 1000 cell surface antigens on a leukocyte distinguishes leukemias of T-cell, B-cell, or myeloid lineage” which is confusing as the instant claim is directed to an assay device comprising a solid support and an array of immunoglobulin molecules. It is unclear what limitation of the device is intended by the recitation of an apparent intended result or intended use of the device. Also, the connection, if any, between the solid support/array of immunoglobulin molecules and the expression pattern of cell surface antigens on a leukocyte is unclear. Clarification of this issue via clearer claim wording and/or amendment is requested. Claims 69 and 71-74 are also rejected due to their dependency from claim 58.

Claims 58 (lines 3 and 5) and 71 (lines 2-3) recite the term “derivative” which is vague and indefinite. It is unclear what “derivative” of an immunoglobulin is intended to be. Clarification of this issue via clearer claim wording is requested. Claims 69 and 71-74 are also rejected due to their dependency from claim 58.

Claim 58 limits the “specificity” of immunoglobulins on the array twice; i.e. to be specific for 7 to about 1000 cell surface marker antigens, and to be specific for cell surface marker antigens selected from the list in Table 4. Based on the phrasing of the claim, it is

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unclear whether each immunoglobulin is to be “specific” to 7-1000 antigens or whether there are 7 to about 1000 immunoglobulins, each of which is specific to a cell surface marker antigen. It is also unclear whether the 7-1000 cell surface marker antigens are the same or different from those listed in Table 4, or whether one is a subset of the other, etc. If different, then it is further unclear whether the immunoglobulins must be specific for BOTH sets, or may be selected independently from either set, or must be specific for some combination of sets, etc. Claim 58 recites the phrase “the array comprises immunoglobulin molecules specific for cell surface marker antigens selected from the list in Table 4” which also lacks clarity. It is unclear if this phrase is intended to mean that the antibodies are to be specific for ALL of the antigens listed in table 4, or are to be specific for only “selected” antigens.

If applicant intends “such that the array comprises at least 7 to about 1000 immunoglobulins, each specific for a cell surface marker antigen, wherein the cell surface marker antigens are those selected from the list recited in table 4,” then this rejection may be overcome by explicitly reciting the limitations intended for the immunoglobulins using language such as that exemplified by the examiner. Applicant is advised that the language is exemplary only, and that all amendments must be fully supported and enabled by the originally filed disclosure. It is also noted that certain embodiments of the claims, such as a single immunoglobulin specific for 7-1000 antigens, may not be enabled. However, as it is unclear what limitations are actually intended, the claims are rejected herein only for lack of clarity. Claims 69 and 71-74 are also rejected due to their dependency from claim 58.

Claims 69 and 72 recite “wherein the subject is a human” and “wherein the subject is a non-human animal”, respectively, which lack clarity. It is unclear how limiting the subject

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further limits the DEVICE of instant claim 58. Clarification of this issue via clearer claim wording is requested.

Claims 72-74 recite the limitation "The method of claim 58" in the first line of each claim. There is insufficient antecedent basis for this limitation in these claims as claim 58 is directed to a device, not a method. Clarification of this issue via clearer claim wording is requested.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tiffany Tabb whose telephone number is (571) 272-0556.

May 30, 2006

MARJORIE A. MORAN
PRIMARY EXAMINER

M. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
6/12/06